
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(D)
of the Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): **August 8, 2018**

Leap Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37990
(Commission
File Number)

27-4412575
(IRS Employer
Identification No.)

47 Thorndike Street, Suite B1-1
Cambridge, MA
(Address of principal executive offices)

02141
(Zip Code)

Registrant's telephone number, including area code: **(617) 714-0360**

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition

On August 8, 2018, Leap Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2018. The full text of the press release issued by the Company in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference to such filing. The information in this Current Report on Form 8-K, including the information set forth under this Item 2.02 and the exhibit hereto, shall not be

deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of Leap Therapeutics, Inc. dated August 8, 2018.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

LEAP THERAPEUTICS, INC.

Dated: August 8, 2018

By: /s/ Christopher K. Mirabelli, Ph.D.
Name: Christopher K. Mirabelli, Ph.D.
Title: Chief Executive Officer and President



Leap Therapeutics Reports Second Quarter 2018 Business Update and Financial Results

Cambridge, MA — August 8, 2018 — Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company developing targeted and immuno-oncology therapeutics, today reported a business update and financial results for the second quarter ended June 30, 2018.

“Over the past few months, we have seen patients in the studies of both of our antibody programs experience clinical responses in combination with checkpoint inhibitors, including in patients who would not be expected to respond to checkpoint inhibitors alone. We look forward to continuing to read out data throughout the second half of 2018 from these ongoing clinical trials, including from our study evaluating DKN-01 in combination with KEYTRUDA® (pembrolizumab) in patients with advanced esophagogastric cancer at the European Society for Molecular Oncology (ESMO) Annual Meeting in October,” commented Christopher K. Mirabelli, Ph.D, President and Chief Executive Officer of Leap Therapeutics. “In addition, we recently announced a TRX518 collaboration with Pfizer and EMD Serono to add to our existing DKN-01 collaborations with Merck and Roche.”

Recent Highlights

Since the end of the first quarter, we have made substantial progress with the development of our product candidates:

- Presented clinical results from our study evaluating DKN-01 in combination with KEYTRUDA® (pembrolizumab) in patients with advanced esophagogastric cancer.
 - Combination has been well tolerated with no dose limiting toxicity.
 - In the high-dose DKN-01 cohort of dose escalation, two of four evaluable patients naïve to anti-PD-1/PD-L1 therapy have had a partial response, with two other evaluable patients having a best response of stable disease.
 - Both of the responding patients have a tumor phenotype which is typically less responsive to anti-PD-1 therapy.
 - Currently enrolling expansion cohorts in patients who are naïve to anti-PD-1/PD-L1 therapy and patients who are refractory to anti-PD-1/PD-L1 therapy.
 - The treatment-naïve cohort has passed the Simon Stage 2 threshold.
 - Enrollment of the full study is expected during the first quarter of 2019.
 - Additional data from this study will be presented at the ESMO 2018 Annual Meeting in October.
- Announced a collaboration agreement with Pfizer and Merck KGaA, Darmstadt, Germany to evaluate TRX518 in combination with BAVENCIO® (avelumab) and cyclophosphamide chemotherapy.
 - Under the terms of the collaboration, we will be conducting a Phase I/II clinical trial in advanced solid tumors including expansion populations in patients with relapsed/refractory ovarian, breast, and prostate cancers.
 - The study is expected to begin enrolling patients in the first quarter of 2019.

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- Presented initial data from our clinical trial evaluating TRX518 in combination with gemcitabine chemotherapy or in combination with KEYTRUDA® (pembrolizumab) or OPDIVO® (nivolumab).
 - The first two patients treated with the higher dose of TRX518 in combination with KEYTRUDA have experienced clinical benefit after the end of two cycles of therapy.
 - Esophageal squamous cell carcinoma patient demonstrated a partial response with a 36% reduction in tumor volume.
 - Ocular melanoma patient experienced stable disease with a 23% reduction in tumor volume.
 - Seven patients have been treated with the lower dose of TRX518 in combination with OPDIVO.
 - Urothelial carcinoma patient who had progressed while on KEYTRUDA has had a partial response with a 39% reduction in tumor volume after the end of two cycles.
 - Four other patients experienced progressive disease, one patient was non-evaluable, and one patient has not yet had any on treatment disease evaluation.
 - Enrollment continues in the dose escalation phase for both the KEYTRUDA and OPDIVO combinations and in the dose expansion phase for the gemcitabine combination.

Selected Second Quarter 2018 Financial Results

Net loss was \$7.4 million for the second quarter of 2018, compared to \$6.9 million for the same period in 2017.

Research and development expenses were \$4.2 million for the second quarter 2018, compared to \$4.9 million for same period in 2017. The decrease of \$0.7 million was primarily due to a decrease of \$0.4 million in manufacturing costs related to clinical trial material, a decrease of \$0.2 million in clinical trial costs and a decrease of \$0.2 million in consulting fees associated with research and development activities. These decreases were partially offset by an increase of \$0.1 million in stock based compensation expense.

General and administrative expenses were \$2.6 million for the second quarter 2018, compared to \$2.1 million for the same period in 2017. The increase of \$0.5 million in general and administrative expenses was primarily due to a \$0.4 million increase in legal, audit and consulting fees associated with corporate and business development activities and an increase of \$0.1 million of stock based compensation expense.

Cash, cash equivalents and marketable securities totaled \$30.5 million at June 30, 2018. Research and development incentive receivables totaled \$1.8 million. The Company believes that its current cash and cash equivalents and the anticipated receipt of the research and development incentive receivable will be sufficient to fund the Company's operating expenses into the fourth quarter of 2019.

About Leap Therapeutics

Leap Therapeutics (NASDAQ:LPTX) is focused on developing targeted and immuno-oncology therapeutics. Leap's most advanced clinical candidate, DKN-01, is a humanized monoclonal antibody targeting the Dickkopf-1 (DKK1) protein, a Wnt pathway modulator. DKN-01 is in clinical trials in patients with esophagogastric cancer, biliary tract cancer, and gynecologic cancers, with an emerging focus on patients with defined mutations of the Wnt pathway and in combination with immune checkpoint inhibitors. Leap's second clinical candidate, TRX518, is a humanized GITR agonist monoclonal antibody designed to enhance the immune system's anti-tumor response that is in two advanced solid tumor studies. For more information about Leap Therapeutics, visit <http://www.leaptx.com> or our public filings with the SEC that are available via EDGAR at <http://www.sec.gov> or via <http://www.investors.leaptx.com/>.

FORWARD LOOKING STATEMENTS

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. These statements include statements relating to Leap's expectations with respect to the development and advancement of DKN-01, TRX518, and other programs, including the initiation, timing and design of future studies, enrollment in future studies, business development, and other future expectations, plans and prospects. Leap has attempted to identify forward looking statements by such terminology as "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "may," "could," "might," "will," "should," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Although Leap believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from our expectations. These risks and uncertainties include, but are not limited to: the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for financing; the ability to complete a financing or form business development relationships to fund our expenses; the outcome, cost, and timing of our product development activities and clinical trials; the uncertain clinical development process, including the risk that clinical trials may not have an effective design or generate positive results; our ability to obtain and maintain regulatory approval of our drug product candidates; our plans to research, develop, and commercialize our drug product candidates; our ability to achieve market acceptance of our drug product candidates; unanticipated costs or delays in research, development, and commercialization efforts; the applicability of clinical study results to actual outcomes; the size and growth potential of the markets for our drug product candidates; our ability to continue obtaining and maintaining intellectual property protection for our drug product candidates; and other risks. Detailed information regarding factors that may cause actual results to differ materially will be included in Leap Therapeutics' periodic filings with the Securities and Exchange Commission (the "SEC"), including Leap Therapeutics' Form 10-K that Leap filed with the SEC on February 23, 2018. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors. Any forward looking statements contained in this release speak only as of its date. We undertake no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA. OPDIVO® is a registered trademark of Bristol-Myers Squibb Company. BAVENCIO® is a registered trademark of Pfizer, Inc.

CONTACT:

Leap Therapeutics, Inc.:
Douglas E. Onsi
Chief Financial Officer
donsi@leaptx.com
617-714-0360

Argot Partners:
Heather Savelle
Mary Jenkins
617-663-4863
heather@argotpartners.com
mary@argotpartners.com

Leap Therapeutics, Inc. Condensed Consolidated Statements of Operations (in thousands, except share and per share amounts)

	Three Months Ended June 30		Six Months Ended June 30	
	2018	2017	2018	2017
	(Unaudited)		(Unaudited)	
Operating expenses:				
Research and development	\$ 4,234	\$ 4,881	\$ 8,465	\$ 11,285
General and administrative	2,603	2,135	4,716	5,939
Total operating expenses	6,837	7,016	13,181	17,224
Loss from operations	(6,837)	(7,016)	(13,181)	(17,224)
Interest income	122	49	199	99

Interest expense	(8)	—	(14)	—
Interest expense - related party	—	—	—	(121)
Australian research and development incentives	243	494	889	891
Foreign currency gains (loss)	(222)	(432)	(366)	36
Change in fair value of warrant liability	(662)	—	(5,513)	—
Net loss	(7,364)	(6,905)	(17,986)	(16,319)
Accretion of preferred stock to redemption value	—	—	—	(244)
Net loss attributable to common stockholders	<u>\$ (7,364)</u>	<u>\$ (6,905)</u>	<u>\$ (17,986)</u>	<u>\$ (16,563)</u>
Net loss per share - basic and diluted	<u>\$ (0.50)</u>	<u>\$ (0.74)</u>	<u>\$ (1.32)</u>	<u>\$ (2.03)</u>
Weighted average common shares outstanding - basic and diluted	<u>14,691,890</u>	<u>9,392,081</u>	<u>13,576,850</u>	<u>8,171,078</u>

Leap Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	<u>June 30,</u> <u>2018</u> <u>(Unaudited)</u>	<u>December 31,</u> <u>2017</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 30,481	\$ 25,737
Research and development incentive receivable	959	1,744
Prepaid expenses and other current assets	608	177
Total current assets	<u>32,048</u>	<u>27,658</u>
Property and equipment, net	111	135
Research and development incentive receivable, net of current portion	851	—
Deferred tax asset	151	158
Other assets	1,246	1,111
Total assets	<u>\$ 34,407</u>	<u>\$ 29,062</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 4,766	\$ 2,622
Accrued expenses	1,261	3,461
Total current liabilities	<u>6,027</u>	<u>6,083</u>
Non Current liabilities:		
Warrant liability	16,245	11,862
Total liabilities	<u>22,272</u>	<u>17,945</u>
Stockholders' equity:		
Common stock, \$0.001 par value; 100,000,000 shares authorized; 14,700,681 and 12,354,014 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	15	12
Additional paid-in capital	160,522	141,770
Accumulated other comprehensive loss	(19)	(268)
Accumulated deficit	(148,383)	(130,397)
Total stockholders' equity	<u>12,135</u>	<u>11,117</u>
Total liabilities and stockholders' equity	<u>\$ 34,407</u>	<u>\$ 29,062</u>

Leap Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)

	<u>Six Months Ended June 30,</u>	
	<u>2018</u>	<u>2017</u>
	<u>(Unaudited)</u>	
Cash used in operating activities	\$ (11,531)	\$ (13,411)
Cash used in investing activities	—	(66)
Cash provided by financing activities	16,013	29,868
Effect of exchange rate changes on cash and cash equivalents	262	(13)
Net increase in cash and cash equivalents	<u>4,744</u>	<u>16,378</u>
Cash and cash equivalents at beginning of period	25,737	793
Cash and cash equivalents at end of period	<u>\$ 30,481</u>	<u>\$ 17,171</u>